Atty Dkt. No.: 10021295-1 USSN: 10/633,611

REMARKS UNDER 37 CFR § 1.111

Formal Matters

Claims 1, 5-7, 10-13 and 41-49 are pending after entry of the amendments set forth herein.

Claims 1-40 were examined. Claims 1-40 were rejected.

Applicants respectfully request reconsideration of the application in view of the amendments and remarks made herein.

No new matter has been added.

The Office Action

In the Official Action of August 26, 2005, claims 15, 22 and 25 were objected to for specified informalities. Claims 15, 22 and 25 have been canceled without prejudice above. Accordingly, the Examiner is respectfully requested to reconsider and withdraw the objection to claims 15, 22 and 25 as being moot.

Claims Rejected Under 35 U.S.C. Section 101

Claims 25-29 were rejected under 35 U.S.C. Section 101 as being directed to non-statutory subject matter. Although Applicants do not agree with this ground of rejection, and do not acquiesce thereto, Applicants have nevertheless canceled claims 25-29, without prejudice, above, in order to advance the prosecution of the instant application. Accordingly, the Examiner is respectfully requested to reconsider and withdraw the rejection of claims 25-29 under 35 U.S.C. Section 101 as being moot.

Claims 1-40 were rejected under 35 U.S.C. Section 101 as lacking patentable utility. The Examiner indicated that the specification fails to disclose any utility for the claimed invention and that there is no well-established utility because there is no description of a specific result of the claimed method. Applicants respectfully disagree. The specification provides many different examples of results that are produced by the present invention and which may be provided to a user. As just one example, page 13, lines 6-17 describe a test request is for a test the results of which are dependent upon known genetic polymorphisms and the array tested contains features for the different polymorphic

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variants of one or more genes. A result generated in this instance may be one which does not provide any indication of feature locations of the array bound to a sample component, but may just state that an organism from which a sample was derived and which sample was exposed to the array, likely does or does not exhibit a particular condition (for example, a disease, presence of a pathogen, particular genetic deficiency, and the like). It is respectfully submitted that these are specifically disclosed results.

The Examiner further asserted that in order for the result of the claimed methods to be useful, one skilled in the art must be aware of the correlation between information received (e.g., signal data from an array) and a goal of the method (conditions to be diagnosed). Applicants respectfully submit that the example referred to above provides a user with such correlation by informing the user that the subject (organism) from which the data was generated, likely does or does not have the condition for which the test was conducted. The system correlates the array identifier with the signal data that is processed, and the results are produced and provided to the user. Further, the claims have been amended to recite providing the user with such results.

In view of the above remarks and the amendments to the claims, the Examiner is respectfully requested to reconsider and withdraw the rejection of claims 1, 5-7, and 10-13 (claims 2-4, 8-9, 14-40 having been canceled without prejudice above) under 35 U.S.C. Section 101 as lacking patentable utility, as being inappropriate.

Claims Rejected Under 35 U.S.C. Section 112, First Paragraph

Claims 37-40 were rejected under 35 U.S.C. Section 112, first paragraph as failing to comply with the enablement requirement. Although Applicants do not agree with this ground of rejection, and do not acquiesce thereto, Applicants have nevertheless canceled claims 37-40, without prejudice, above, in order to advance the prosecution of the instant application. Accordingly, the Examiner is respectfully requested to reconsider and withdraw the rejection of claims 37-40 under 35 U.S.C. Section 112, first paragraph, as being moot.

Claims Rejected Under 35 U.S.C. Section 112, Second Paragraph

Claims 1-24 were rejected under 35 U.S.C. Section 112, second paragraph as being indefinite. In response thereto, claim 1 has been amended to change "the array" to --the chemical array—for which there is literal antecedent basis. In response to the rejection, claim 6 has been amended to recite that the

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at least one instruction contains an instruction for one of: processing a sub-array pattern, and processing or reading only a sub-array, without specification of a manner of processing. Claim 23 has been canceled without prejudice. Claims 8, 9 and 20 have been canceled without prejudice. Claim 10 has been amended to clarify that "each" in "each retrievable" refers to each sub-array pattern. With regard to claim 11, the rejected term "acquired" has been deleted. Claim 12 has been amended to delete the new step of generating a result, and instead recites transmitting the results recited in claim 1. Claims 16, 18 and 19 have been canceled without prejudice. Claims 25-29 and 37-40 have been canceled without prejudice.

In view of the above amendments and remarks, the Examiner is respectfully requested to reconsider and withdraw the rejection of claims 1, 5-7 and 10-13 (claims 2-4, 8-9 and 14-24 having been canceled without prejudice) under 35 U.S.C. Section 112, second paragraph, as being indefinite, as being no longer appropriate.

Claims Rejected Under 35 U.S.C. Section 102(b) (Milosavijevic)

Claims 37-40 were rejected under 35 U.S.C. Section 102(b) as being anticipated by Milosavijevic, WO 01/31333. Although Applicants do not agree with this ground of rejection, and do not acquiesce thereto, Applicants have nevertheless canceled claims 37-40, without prejudice, above, in order to advance the prosecution of the instant application. Accordingly, the Examiner is respectfully requested to reconsider and withdraw the rejection of claims 37-40 under 35 U.S.C. Section 102(b) as being anticipated by Milosavijevic, WO 01/3133325, as being moot.

Claims Rejected Under 35 U.S.C. Section 103(a) (Milosavijevic in view of Venkatesan)

Claims 1-40 were rejected under 35 U.S.C. Section 103(a) as being unpatentable over Milosavijevic, WO 01/31333 in view of Venkatesan, U.S. Patent No. 6,282,550. The Examiner asserted that Milosavijevic discloses a step of retrieving from a memory or reading an array identifier for an array of probes, forwarding the array identifier and a request for a test to a remote location, and receiving instructions for processing data obtained from an array from a remote location. In view of the amendment of claim 1 and the remarks that follow, Applicants respectfully request reconsideration and withdrawal of this rejection.

Milosavijevic discloses a method of ordering custom made microarrays over the internet. A

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customer provides biological samples and identifies genome sequences of interest. The service provider obtains the biological samples and genome sequences, provides microarrays containing the identified genome sequences, and applies the biological samples to the microarrays. The client receives results from analyzing the microarray experiments generated and analyzed by the service provider, over the internet.

To the contrary, Applicants' invention provides an array that is useable for many different tests, wherein the features on the array are arranged in different subarray patterns. Claim 1, as currently amended, recites that signal data is obtained from a chemical array, and that a test request is provided for reading or processing signal data from a sub-array of probes on the chemical array. An instruction is retrieved based on the test request, from a memory containing a plurality of instructions, each retrievable by a different test request. The signal data **for the sub-array** is then read or processed according to the retrieved instruction. It is respectfully submitted that Milosavijevic fails to disclose or suggest such an array, but rather teaches away from such an array by providing a system for custom designing an array for a specific purpose.

Milosavijevic, in contrast, only receives an order from a customer for producing an array and then analyzing it. Milosavijevic does not receive a test request from the customer to read or process a sub-array of an array, since a primary purpose of Milosavijevic's method is to produce the custom array according to the customer's needs. Nor does Milosavijevic disclose or suggest that the customer sends a test request, from which the service provider could retrieve an instruction for reading or processing signal data from a sub-array of an array. The Examiner further asserted that Milosavijevic discloses an instruction comprising a sub-array pattern indicating that only the sub-set data are to be analyzed. The Examiner referred to page 26, line 15 through page 27, line 13, as support for this assertion. This portion of Milosavijevic discloses analysis tools for analyzing project data. An Interactive Query Builder allows a user to select rows, corresponding to samples for selecting subsets of data from a table of project data, for analysis. An Analytical Spreadsheet similarly allows manual selection of subsets. However, neither of these functions is based on a test request provided and from which an instruction is retrieved, which instruction is used to read or process the signal data for a sub-array. The selection of rows is a selection of samples and their associated data from a project data table, not from a chemical array. Thus, this is neither a test request, nor an instruction for reading or processing signal data from a sub-array of an array, as each sample selected causes the entire array for that sample to be considered during the further analysis.

Venkatesan et al. describes a process for correlating customer request and suppliers capabilities

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for custom synthesis of polymers, and thus also lacks any teaching or disclosure of the features that have been noted to be lacking in Milosavijevic above. Since all of the other rejected claims that are still pending depend from claim 1, it is respectfully submitted that these claims also patentably define over the cited combination of references for at least the same reasons noted with regard to claim 1.

Accordingly, in view of the above amendments and remarks, the Examiner is respectfully requested to reconsider and withdraw the rejection of claims 1, 5-7 and 10-13 (claims 2-4, 8-9 and 14-40 having been canceled without prejudice) under 35 U.S.C. Section 103(a) as being unpatentable over Milosavijevic, WO 01/31333 in view of Venkatesan, U.S. Patent No. 6,282,550, as being inappropriate.

Claims Rejected Under 35 U.S.C. Section 103(a) (Anderson in view of Venkatesan)

Claims 1-40 were rejected under 35 U.S.C. Section 103(a) as being unpatentable over Anderson, WO 01/80155 in view of Venkatesan, U.S. Patent No. 6,282,550. The Examiner asserted that Anderson discloses a method for custom-designed biological array design and analysis, including steps of retrieving or reading an array identifier, forwarding the identifier and a request for a test to a remote location, receiving instruction from a remote location, reading signal data according with the instructions, and reporting such reading and forwarding.

Like Milosavijevic, the method of Anderson allows a customer to design a biochip array by specifying the sequence content motif ("oligonucleotide sequences, polypeptide sequences, receptor binding sequences, or antigens to be bound [to the biochip]" – see page 4, lines 27-29) to be placed on the array. The sequence content motif is sequence data for **the entire array**. A computer that is remote from the customer then sends the sequence content motif to an automated array fabrication unit. After making the array, the customer exposes the array to test samples. An assay of the array is performed by the customer, using an assay instrument provided by the makers of the system. The assay data are sent to the computer remote from the user, where they are compared to the sequence content motif that was used to make the array. The processed data may then be sent to the customer's computer. Anderson discloses only comparing the assay data with the sequence motif that was constructed according to the customers order for the production of the **entire** array from which the assay data has been generated. Anderson does not provide a plurality of instructions for reading or processing signal data for probes from a sub-array of an array, each instruction retrievable by a different test request, which instructions are selectable according to the test request supplied to the provider's site. Nor does Anderson disclose or suggest such test requests in any manner.

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Venkatesan et al. describes a process for correlating customer request and suppliers' capabilities for custom synthesis of polymers, and thus also lacks any teaching or disclosure of the features that have been noted to be lacking in Anderson above. Since all of the other rejected claims that are still pending depend from claim 1, it is respectfully submitted that these claims also patentably define over the cited combination of references for at least the same reasons noted with regard to claim 1.

Accordingly, in view of the above amendments and remarks, the Examiner is respectfully requested to reconsider and withdraw the rejection of claims 1, 5-7 and 10-13 (claims 2-4, 8-9 and 14-40 having been canceled without prejudice) under 35 U.S.C. Section 103(a) as being unpatentable over Anderson, WO 01/80155 in view of Venkatesan, U.S. Patent No. 6,282,550, as being inappropriate.

Claims Rejected Under 35 U.S.C. Section 103(a) (Catell in view of Venkatesan)

Claims 1-4, 6-21 and 23-40 were rejected under 35 U.S.C. Section 103(a) as being unpatentable over Catell, U.S. Patent No. 6,180,351 in view of Venkatesan, U.S. Patent No. 6,282,550. The Examiner asserted that Catell discloses a method for fabricating an addressable array, including steps of retrieving an array identifier and forwarding the identifier and a test request to a remote location (col. 4, lines 11-42), receiving instructions in response from the remote location, and processing signal data according to the instructions.

Catell discloses exposing a test sample to an array, then scanning and interrogating the array to obtain interrogation results. An array identifier associated with the array is read and the array layout is retrieved from memory, the layout being linked by the array identifier. The array layout can then be used to access the array for obtaining feature information. However, Catell does not disclose or suggest providing a test request for processing or reading signal data from a sub-array of probes on the chemical array, retrieving an instruction from a plurality of instructions stored in a memory, each instruction retrievable with a different test request, based on the test request provided, and reading or processing the signal data for the sub-array according to the retrieved instruction.

Venkatesan et al. describes a process for correlating customer request and suppliers capabilities for custom synthesis of polymers, and thus also lacks any teaching or disclosure of the features that have been noted to be lacking in Catell above. Since all of the other rejected claims that are still pending depend from claim 1, it is respectfully submitted that these claims also patentably define over the cited combination of references for at least the same reasons noted with regard to claim 1.

Accordingly, in view of the above amendments and remarks, the Examiner is respectfully

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requested to reconsider and withdraw the rejection of claims 1, 6-7 and 10-13 (claims 2-4, 8-9 and 14-40 having been canceled without prejudice) under 35 U.S.C. Section 103(a) as being unpatentable over Catell, U.S. Patent No. 6,180,351 in view of Venkatesan, U.S. Patent No. 6,282,550, as being inappropriate.

It is further respectfully submitted that new claims 41-49 also patentable define over the art of record. Claims 41-49 depend from claim 1 and, it is respectfully submitted, patentably define over the art of record for at least the same reasons provided with regard to claim 1 above. Further, claim 41 recites providing an array identifier that identifies the chemical array, and wherein said retrieving an instruction is performed based on said test request and said array identifier, features which are neither taught or suggested by the art of record. Claim 45 recites that at least one instruction comprises an indication that only signal data from feature locations in the sub-array need be read or processed, a feature which is neither taught nor suggested by the art or record. Claim 47, recites that at least one instruction comprises an instruction on processing read signal data, and claim 48 recites that at least one instruction comprises a data processing instruction or a parameter for a method which performs array signal data interpretation. These features, as applied to reading or processing signal data for a sub-array of a chemical array, are neither taught nor suggested by the art of record.

Conclusion

Applicants submit that all of the claims are in condition for allowance, which action is requested. If the Examiner finds that a telephone conference would expedite the prosecution of this application, please telephone the undersigned at the number provided.

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The Commissioner is hereby authorized to charge any underpayment of fees associated with this communication, including any necessary fees for extensions of time, or credit any overpayment to Deposit Account No. 50-1078, order number 10021295-1.

Respectfully submitted,

LAW OFFICE OF ALAN W. CANNON

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